UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE, Plaintiff, -against- CENTERS FOR DISEASE CONTROL AND PREVENTION, AND DEPARTMENT OF HEALTH & HUMAN SERVICES, Defendants.	Civil Action No. 2:23-cv-00102

PLAINTIFF'S BRIEF AND MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The issue presented to this Court is purely a question of law: namely, whether Centers for Disease Control and Prevention ("**CDC**") can withhold or otherwise refuse to disclose data that was collected from Americans and used to justify CDC's claims that Covid-19 vaccines are "safe and effective." It is undisputed that CDC denied Plaintiff's initial Freedom of Information Act ("**FOIA**") request for all data obtained from v-safe users from the free-text fields within the v-safe program for Covid-19 vaccines. Dkt. 1 ¶62. It is undisputed that CDC has failed to respond to Plaintiff's January 13, 2023 appeal challenging that agency decision failed to establish the validity of its claimed withholdings as it is obligated to do pursuant to FOIA. Dkt. 1 ¶66. And it is undisputed that CDC's legal counsel has openly stated to undersigned counsel that the agency will not produce the data short of a court order. Appendix ("App.") at APP0004 ¶ 15. Because CDC's refusal to produce the data violates the Freedom of Information Act ("**FOIA**"), Plaintiff requests that this Court grant it summary judgment and, thus, access to the data to which it and all Americans are entitled.

As background, in December 2020, the Food and Drug Administration ("**FDA**") issued emergency use authorizations ("**EUA**") for the first COVID-19 vaccines, followed by additional authorizations and licensures in rapid succession thereafter. Dkt. 1 ¶28. While FDA authorizes and approves vaccines, it is CDC, an agency within the U.S. Department of Health & Human Services ("**HHS**"), that is charged with monitoring the safety of these vaccines. Dkt. 1 ¶32.

The federal government mandated that hundreds of millions of Americans receive these products and has given the pharmaceutical companies financial immunity for injuries caused by these products. Dkt. 1 ¶30. Mandating that millions of Americans inject a product for which they

cannot hold the manufacturer liable for injuries demands complete transparency, especially when it comes to the data underlying claims of the product's safety. Dkt. 1 ¶31.

The Freedom of Information Act ("**FOIA**") exists precisely so that Americans can obtain transparency and, in this case, obtain the core data which supports CDC's claims that these products are safe. Dkt. 1 ¶4.

CDC claims that the current "COVID-19 vaccines are being administered under the most intensive vaccine safety monitoring effort in U.S. history,"[1] and because its existing Vaccine Adverse Events Reporting System ("**VAERS**") cannot determine causation and was otherwise unreliable,[2] it deployed a new safety monitoring system for the COVID-19 vaccines: v-safe. Dkt. 1 ¶5.

V-safe is CDC's premier system for tracking the safety of COVID-19 vaccines. Dkt. 1 ¶6. It is a smartphone-based program that allows vaccine recipients to "tell CDC about any side effects after getting the COVID-19 vaccine."[3] Its purpose, as explained by CDC, "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[4] Dkt. 1 ¶6.

While v-safe collected a limited amount of safety information from its approximately 10 million users using check-the-box options, the program also provided a few free-text fields (limited

[1] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf.

[2] *Id.*

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[4] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V6-508.pdf at 5.

to 250 characters each) for users to provide additional safety information. CDC has represented that it received 7.8 million free-text entries from v-safe users. Dkt. 1 ¶7.

These free-text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines because they were collected from a known universe of users directly reporting their symptoms and reactions. Thus, the rate at which an adverse event is reported can be calculated and relied upon. Dkt. 1 ¶8. Moreover, unlike other safety data the government has relied upon, v-safe data is not filtered through the companies selling the vaccines which, in turn, removes conflicts of interest that could potentially influence the data. Dkt. 1 ¶8.

Delays in disclosing this data prevent the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. Dkt. 1 ¶9. These delays compromise the public's significant recognized interest in, *inter alia*, transparency and informed consent, and their ability to assess potential harms, develop strategies to prevent such harms, and treat those who have already been harmed.[5] That is, for example, the core mission of numerous groups that have formed to treat individuals injured by COVID-19 vaccines. Dkt. 1 ¶9; App. at APP0169 ¶ 14.

For example, React19 is a group comprised of over 30,000 individuals, including hundreds of medical professionals, who have been seriously injured by a COVID-19 vaccine. They are desperately seeking reliable data that can help explain the harms suffered among their members, which are currently only being observed in a non-systematic fashion. Until these harms are

[5] A right to informed consent has been codified in jurisdictions across the United States. *See, e.g.*, Tex. Civ. Prac. & Rem. Code § 74.101 ("recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent").

scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harm – even if there are tens of thousands – without systematic datasets, the medical health establishment considers these complaints as mere anecdotes. Thus, these harms are allowed to continue dangerously unabated; this will not change until the public, including groups like React19, can get the data needed to systematically show what harms are caused by COVID-19 vaccines; they desperately need v-safe's free-text data to have a systematic dataset that may scientifically validate their harms so that the medical community will acknowledge them and then provide medical care. Dkt. 1 ¶10; App. at APP0169 ¶ 16.

Transparency is even more critical because CDC has added the COVID-19 vaccines to its routine childhood immunization schedule.[6] This policy will likely cause states to create policies that grant or restrict certain privileges, such as attending school, based on a child's COVID-19 vaccination status. Dkt. 1 ¶11. Parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent. Dkt. 1 ¶11.

The information sought is also more urgent than ever because the federal government has implemented policies and a multi-billion-dollar messaging campaign designed to promote the

[6] *See* https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.

public's uptake of COVID-19 vaccines and boosters.[7] However, as it promotes these products, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms of receiving these medical products. This transparency will allow consumers to make the most informed decision possible. Dkt. 1 ¶12.

In line with its sole mission, and pursuant to FOIA, Plaintiff sought from CDC: "**All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry**." Dkt. 1 ¶15; App. At APP0170 ¶ 20. CDC refused to disclose the data claiming "the agency lacks the resources to manually review the data collected." Dkt. 1 ¶15; App. at APP0170 ¶ 21.

As outlined more fully below, CDC has violated and continues to violate FOIA by failing to respond to Plaintiff's appeal, wrongly denying Plaintiff's fee waiver, failing to establish the validity of its claimed withholdings and, most importantly, by continuing to withhold data that is not exempt from disclosure and that the American public has every right to see.

FACTS

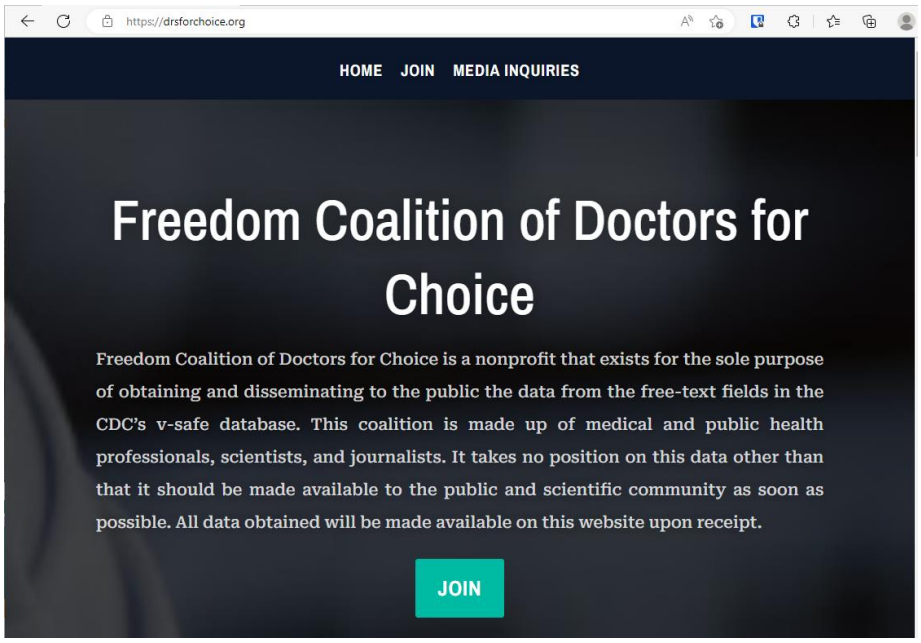
I. The Freedom Coalition

Plaintiff Freedom Coalition of Doctors for Choice ("**Freedom Coalition**" or "**Plaintiff**") is a not-for-profit that was formed and exists for the sole purpose of obtaining and disseminating to the public the v-safe free-text data. This coalition is made up of medical and public health professionals, scientists, and journalists. It takes no position on this data other than that it should be made available to the public and scientific community as soon as possible. All data obtained

[7] *See* e.g. https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

will be made available on its website, www.drsforchoice.org, upon receipt. Dkt. 1 ¶14; App. at APP0166 ¶ 5.

As provided on its website, its mission is as follows:



Dkt. 1 ¶19; App. at APP0167 ¶ 6.

Freedom Coalition currently has 91 members, including at least 46 medical doctors, 16 PhDs, 21 nurse practitioners or registered nurses, as well as professors from medical schools, including from UCLA and the University of Texas. Dkt. 1 ¶20; App. at APP0167 ¶ 7.

At all times relevant hereto, Freedom Coalition's headquarters is and has been at 600 S Tyler St, Suite 2100 #177, Amarillo, TX 79101 and its most recent board meeting was held on March 29, 2023 at its headquarters in Amarillo, TX, which is the usual and customary location of its board meetings. The Freedom Coalition has six board members. Three of its board members reside in Amarillo, Texas (Drs. Pia and Rolf Habersang, and Dr. Deborah Moore), and a fourth works in Amarillo, Texas (Dr. Richard Bartlett). Dkt. 1 ¶21; App. at APP0167 ¶ 8.

Dr. Richard Bartlett is an emergency room physician practicing in Amarillo and Lubbock, Texas. Dr. Bartlett identified and advocated for the use of budesonide in the treatment of COVID-19, which has become a treatment option in hospitals across the country, including Odessa Medical Center and Odessa Regional Medical Center. The therapeutic effect of budesonide was confirmed by Oxford University in multiple randomized controlled trials, including the STOIC TRIAL in which Oxford concluded that 90% of COVID hospitalizations could have been prevented with budesonide.[8] Dkt. 1 ¶22; App. at APP0166 ¶ 1, 4.

Dr. Deborah L. Moore lives in Amarillo, Texas and has her medical office at 6141 West Amarillo Boulevard**,** Amarillo, Texas 79106. Dr. Moore is a family medicine doctor and is the physician-owner and founder of a well-respected family medicine practice in Amarillo. Dr. Moore received her medical degree from Texas A&M Health Science Center College of Medicine and recently published a book titled *Covid Treatment: A Clinician's Guide and Commentary on the Management of Covid-19* based on her clinical experience treating patients with COVID-19. Dkt. 1 ¶23; App. at APP0168 ¶ 9.

Pia Habersang, EdD, CNS, MSN, APRN is a primary care provider with over 40 years of experience with children in hospital and outpatient settings. In 2013, Dr. Habersang founded the Pediatric Wellness Center of Amarillo located at 1901 Medi Park Drive, Suite # 110, Amarillo, TX, where she currently practices. Her Doctorate in Child and Youth Studies prepared her to apply knowledge of early childhood developmental milestones throughout adolescence into primary care. Dkt. 1 ¶24; App. at APP0168 ¶ 10.

Rolf Habersang, MD, MPH, and TM is a physician in Amarillo. He previously specialized in pediatric critical care medicine in Amarillo and was affiliated with multiple hospitals in the area.

[8] *See* https://pubmed.ncbi.nlm.nih.gov/33844996/.

He received his medical degree from University of Basel Switzerland. He has been practicing and teaching since 1973 as a Professor in the Department of Pediatrics at Texas Tech University Health Sciences Center. In 2002, Dr. Habersang founded Integrated Complementary Alternative Medicine in Amarillo, where he takes care of mostly adult patients, while still seeing some patients at Texas Tech on a part-time basis. Dr. Habersang is also the supervising and supportive physician at the Pediatric Wellness Center of Amarillo (founded in 2013), located at 1901 Medi Park Dr. Suite # 110, Amarillo, TX where he co-manages patient care with Dr. Pia Habersang. Dkt. 1 ¶25; App. at APP0168 ¶ 11.

Camilla Glenn, APRN, FNP-C is a primary care provider practicing in Lubbock, Texas who worked for a medical organization that laid her off because they disfavored her providing informed consent to patients regarding COVID-19 vaccines. Dkt. 1 ¶26; App. at APP0169 ¶ 12.

Dr. Paul Thomas is a general surgeon practicing in Lubbock, Texas and the founder of Operation H.O.P.E. USA, a non-profit that, among other things, provides medical care in areas of the world where there may be scant or no capable medical service. Dkt. 1 ¶27; App. at APP0169 ¶ 13.

II. COVID-19 Vaccines

In December 2020, FDA issued EUAs for the Pfizer-BioNTech and Moderna COVID-19 vaccines.[9] Dkt. 1 ¶28. In February 2021, FDA issued an EUA for the Janssen COVID-19 vaccine

[9] *See* https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

and other authorizations and licensures of COVID-19 vaccines followed in succession thereafter.[10] Dkt. 1 ¶28.

These products were then mandated on more than 100 million Americans under the threat of losing their jobs, being separated from the military, being excluded from educational institutions, and from otherwise participating in civil society.[11] The federal government has, for example, issued mandates for private employees, public employees, and the military, although many of these have since been enjoined or rescinded.[12] Dkt. 1 ¶29.

While mandating this product, the federal government has also given the pharmaceutical companies selling these vaccines, and all those associated with administering and promoting them, complete legal immunity for any injury caused by these vaccines. 42 U.S.C. § 247d-6d (providing that any "manufacturer" of "any vaccine, used to . . . prevent or mitigate COVID-19" shall be "immune from suit and liability under Federal and State law with respect to all claims . . . resulting from . . . [its] use by an individual"). These pharmaceutical companies are even immune from liability for willful misconduct unless the federal government—which promoted, licensed, and mandated this product—first brings this claim. *Id*.

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[10] *See* https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine; https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine; https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted.

[11] https://www.whitehouse.gov/covidplan/.

[12] https://www.whitehouse.gov/covidplan/; https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard; https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination; https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF.

III. V-Safe

Because the government has been and continues to be engaged in a vigorous effort to get these vaccines into the arm of nearly every American, by mandate or otherwise, it is essential that these products are safe and afford the American people transparency regarding the data supporting that assurance. Dkt. 1 ¶31.

CDC is the primary federal agency responsible for monitoring the safety of COVID-19 vaccines and assures the public that "COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**[.]"[13] Dkt. 1 ¶32.

CDC's premier system for monitoring the safety of COVID-19 vaccines is v-safe, a smartphone-based program[14] which uses "text messages and web surveys to ask how [users] feel, including if [users] experience any side effects after vaccination."[15] As explained by CDC, the program "helps CDC gather important information and monitor any potential side effects in real time so scientists can quickly study them and determine if there is a safety concern with a particular vaccine."[16] CDC ironically represents that "[t]his information helps [it] communicate **timely and transparent information** about the safety of vaccines to public health officials, healthcare providers, and **the public**."[17] Dkt. 1 ¶33.

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[13] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf.

[14] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html (listing v-safe as one of the ways "CDC expanded and strengthened the country's ability to monitory vaccine safety").

[15] *Id.*

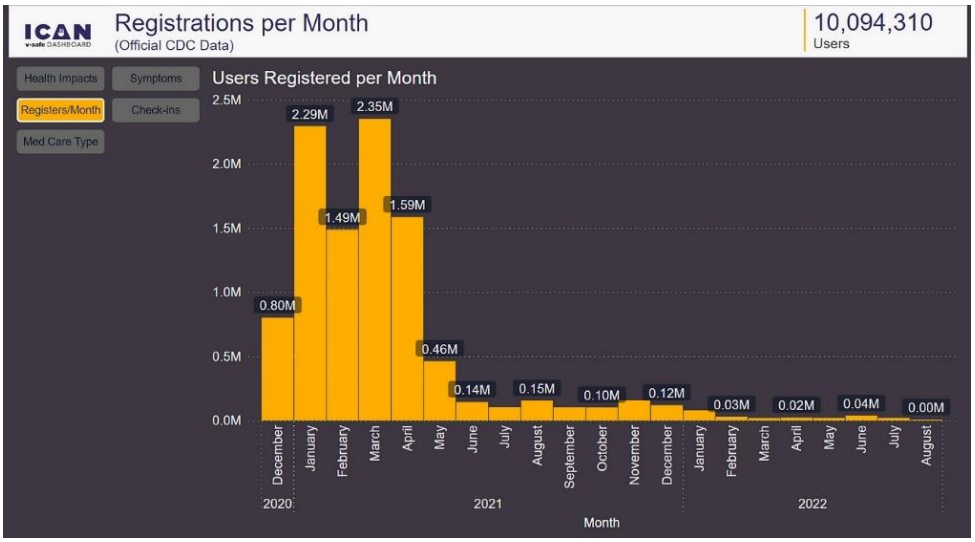
[16] *Id.*

[17] *Id* (emphasis added).

On November 19, 2020, CDC published a protocol for developing v-safe titled "V-safe active surveillance for COVID-19 vaccine safety" (the "**V-Safe Protocol**").[18] The V-Safe Protocol explains that "[t]he purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[19] Dkt. 1 ¶34.

IV. V-Safe Users

V-safe was launched simultaneously with the EUA of the first COVID-19 vaccine in December 2020. Nine million of the approximate 10 million users who registered for v-safe did so between December 2020 and April 2021. The following chart breaks down the number of new v-safe users by month:[20]



Dkt. 1 ¶35.

[18] https://web.archive.org/web/20210102024902/https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[19] *Id.* at 1.

[20] https://icandecide.org/v-safe-data/.

This period from December 2020 to April 2021 was a time when there was high enthusiasm for, and nobody was yet mandated to receive, the vaccine. Most v-safe users were likely enthusiastic about the vaccine and signed up to participate in its roll-out, not to report issues. Dkt. 1 ¶36.

The data submitted by 10 million v-safe users, therefore, is likely a good reflection of the experience of the larger population of 265 million Americans who received at least one dose of a COVID-19 vaccine. The 10 million v-safe users, if anything, may have been prone to *under*report health impacts, not overreport. Dkt. 1 ¶37.

V. The Data V-Safe Collects

V-safe collects COVID-19 vaccine safety information in two ways:

(1) check-the-box options limited to two categories of information, (a) symptoms and (b) health impacts, and

(2) free-text fields.

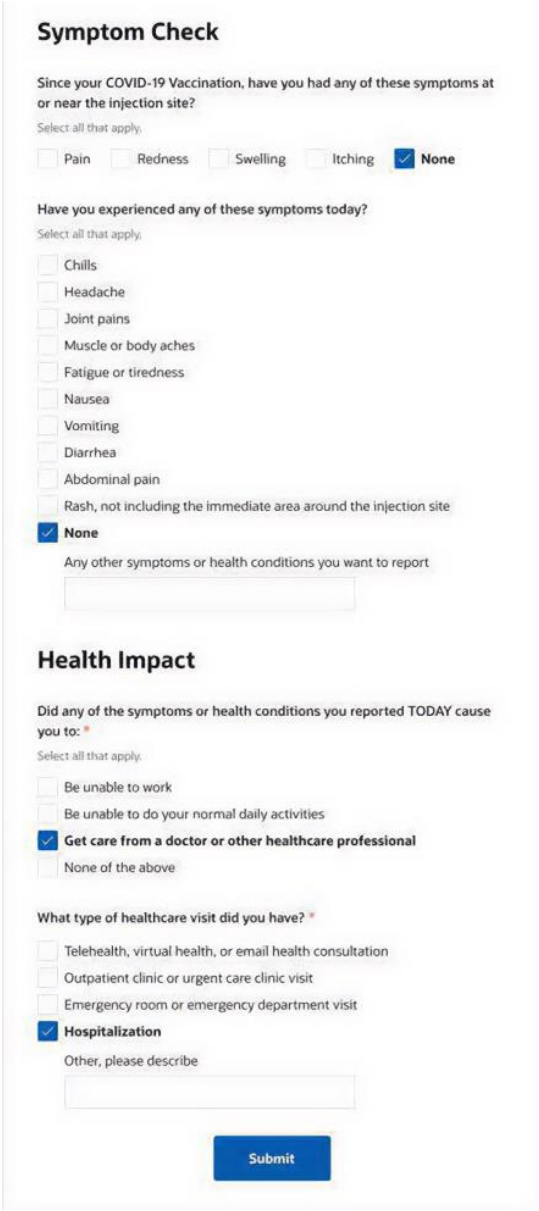
Dkt. 1 ¶38.

Regarding symptoms collected using check-the-box options, v-safe users are asked to select one or more of 10 listed symptoms that occurred within the first week after vaccination. These symptoms are those that CDC says are normal after vaccination and are actually a sign the vaccine is working by producing an immune response. As CDC explains: "Any side effects from getting the vaccine are normal signs the body is building protection."[21] Meaning, the check-the-box symptoms data collected by v-safe was effectively useless for assessing safety of the COVID-19 vaccines. Indeed, the 10 million v-safe users reported over 70 million check-the-box symptoms,

[21] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html.

and this did not raise any concerns for CDC as seen from the numerous studies CDC published with this data evidencing these high rates.[22] Dkt. 1 ¶39.

Here is an image of a survey sent to v-safe users during the first week after injection:



Symptom Check

Since your COVID-19 Vaccination, have you had any of these symptoms at or near the injection site?

Select all that apply.

☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☑ **None**

Have you experienced any of these symptoms today?

Select all that apply.

☐ Chills
☐ Headache
☐ Joint pains
☐ Muscle or body aches
☐ Fatigue or tiredness
☐ Nausea
☐ Vomiting
☐ Diarrhea
☐ Abdominal pain
☐ Rash, not including the immediate area around the injection site
☑ **None**

Any other symptoms or health conditions you want to report

Health Impact

Did any of the symptoms or health conditions you reported TODAY cause you to: *

Select all that apply.

☐ Be unable to work
☐ Be unable to do your normal daily activities
☑ **Get care from a doctor or other healthcare professional**
☐ None of the above

What type of healthcare visit did you have? *

☐ Telehealth, virtual health, or email health consultation
☐ Outpatient clinic or urgent care clinic visit
☐ Emergency room or emergency department visit
☑ **Hospitalization**

Other, please describe

Submit

[22] *See e.g.*, https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7039e4.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e2.htm; https://jamanetwork.com/journals/jama/fullarticle/2778441; https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm; https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm.

Dkt. 1 ¶40.

The only other check-the-box safety information collected (other than symptoms) was whether users reported needing medical care, missed school or work, or could not perform normal daily activities (the "**health impact data**"). If a user selected that he or she needed medical care, the user was asked to select whether he or she sought telehealth, urgent care, emergency care, or were hospitalized (as seen in the image above). Dkt. 1 ¶41.

The health impact data, unlike the check-the-box symptoms data which was collected for only the first week after injection, was collected weekly for the first six weeks after injection and then at 3, 6, and 12 months. Since CDC dubbed v-safe a "real time" surveillance program, presumably this is the data CDC would use to rapidly detect any safety issues.[23] Dkt. 1 ¶42.

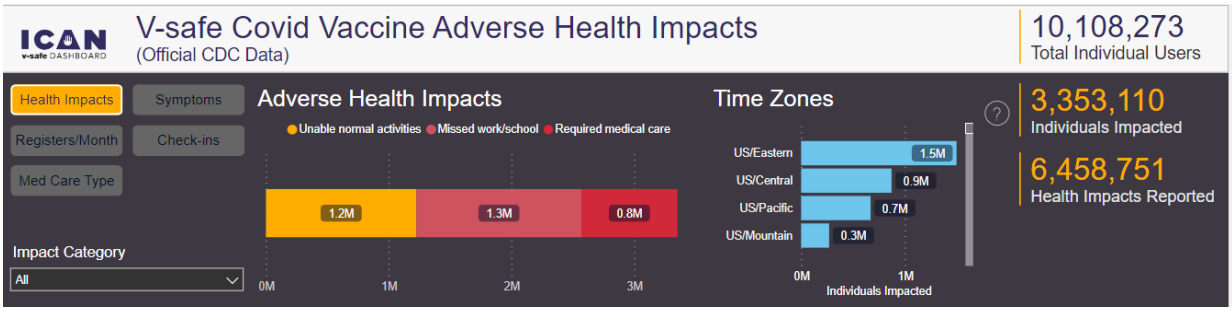
Since 2021, CDC has published over 20 studies to support its claim that COVID-19 vaccines are safe. The main data used in these studies is v-safe's health impact data, with a focus on the rate of people who reported needing medical care after the vaccine. The studies formed the core of CDC's support for the safety of COVID-19 vaccines, however, they only report the *first week* of health impact data after injection. This is, at best, highly misleading because CDC is well aware that injuries from COVID-19 vaccines can occur well after the first week.[24] Dkt. 1 ¶43.

When CDC finally released the check-the-box data to the public, after over two years of legal demands by another group and a federal lawsuit, the data it hid from the public for over two years showed that 7.7% of v-safe users reported needing medical care after a COVID-19 vaccine

[23] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html ("These platforms give CDC scientists information about the safety of COVID-19 vaccines in real time.").

[24] For example, myocarditis can arise at least 42 days after vaccination, *see* https://pubmed.ncbi.nlm.nih.gov/34614329/ at Figure 1. Thrombosis with thrombocytopenia syndrome (TTS), which can also be caused by the COVID-19 vaccine, can arise up to 18 days after vaccination. *See* https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-12-16/02-COVID-See-508.pdf at slide 16.

and an additional 25% of v-safe users who reported missing school or work or being unable to perform normal activities after the injection.[25] Dkt. 1 ¶44.



Dkt. 1 ¶44.

While the public is rightly concerned about these very high rates of reported health impacts, **Freedom Coalition is seriously concerned about the fact that CDC was not transparent about this information with the public**—that it hid the real rates of health impact from COVID-19 vaccines from the public for over two years while misleadingly revealing only the first week of data. Freedom Coalition finds this lack of transparency deeply troubling and wants the full v-safe dataset made public immediately so that independent scientists can review this data—paid for by the American people—to assess what injuries COVID-19 vaccines may cause in order to prevent further injuries and advance treatment for those injured. Dkt. 1 ¶45.

CDC has published two studies the Freedom Coalition can identify that involve free-text data. The first involves menstrual irregularities and vaginal bleeding.[26] In this study, 63,815 v-safe users reported irregularities in the timing and severity of menstruation and vaginal bleeding in the free-text fields. CDC concluded that it "is unable to characterise the relationship of these symptoms to COVID-19 vaccination,"[27] but it could not objectively reach this conclusion as it had previously

[25] https://icandecide.org/v-safe-data/.

[26] *See* https://pubmed.ncbi.nlm.nih.gov/35961858/.

[27] *Id.*

declared these products "safe" and that there is "no evidence that COVID-19 vaccines impact fertility."[28] The second study involves review of free-text responses on day 14 after injection for reports of the same list of 10 symptoms collected during the first week using check-the-box questions.[29] CDC reviewed a total of 245,606 free-text entries to collect what is essentially pointless data regarding symptoms it says are common and expected after vaccination. Dkt. 1 ¶46.

Independent scientists again need the requested free-text data—data that actually provides critical information to assess the safety of the COVID-19 vaccines—to conduct meaningful studies. Dkt. 1 ¶47.

VI. CDC Designed V-Safe to Hide Important Data in the Free-Text Fields

CDC could have made v-safe a rapid and robust safety system by simply including check-the-box options for adverse events of concern (*e.g.*, a check-the-box option for myocarditis or chest pain). In fact, the first version of the V-Safe Protocol, prior to the program's launch, identified adverse events of special interest (**"AESI**") in a chart titled Prespecified Medical Conditions:

[28] http://web.archive.org/web/20220304222019/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/planning-for-pregnancy.html (archived CDC page from March 4, 2022). Compare with same CDC page from February 28, 2022: "Results from recent research studies show that people who menstruate **may observe small, temporary changes in menstruation** after COVID-19 vaccination, including: Longer-lasting menstrual periods, Shorter intervals between periods, Heavier bleeding than usual. **Despite these temporary changes in menstruation, there is no evidence that COVID-19 vaccines cause fertility problems."** https://www.cdc.gov/coronavirus/2019-ncov/vaccines/planning-for-pregnancy.html.

[29] *See* https://pubmed.ncbi.nlm.nih.gov/34763946/.

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

Dkt. 1 ¶48.

CDC also identified all but two (pregnancy and coagulopathy) of these AESIs in an October 22, 2020 presentation titled "CDC post-authorization/post-licensure safety monitoring of COVID-19 vaccines."[30] Many of these AESIs were also identified in a July 2020 NEJM study,[31] as well as in an October 16, 2020 JAMA article.[32] Dkt. 1 ¶49.

Despite CDC itself directly identifying these adverse events as harms of special interest before the launch of v-safe, it did not include check-the-box options for these harms *or* for common symptoms from these harms in the system. Dkt. 1 ¶50.

CDC could have taken advantage of this incredible opportunity—wherein v-safe was already capturing health data from over 10 million users—to easily include these AESIs as check-the-box options for v-safe users. This would have enabled CDC and the scientific community to

[30] *See* https://cacmap.fda.gov/media/143530/download at 31.

[31] *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7377258/#ap2.

[32] *See* https://jamanetwork.com/journals/jama/fullarticle/2772137.

easily calculate a rate for which v-safe users had myocarditis, or other adverse events that had been prespecified by CDC as potential problems (*e.g.*, strokes, seizures, etc.). Dkt. 1 ¶51.

Instead, CDC purposely chose to limit potential reporting of any such adverse events to the free-text fields knowing full well that, among other issues, fewer people would report issues in a free-text field (versus a check-the-box option) and this free-text data would be more difficult to standardize. In that regard, CDC did not design this system with the interests of the public in mind, but rather its own interest to assure control of the data so it can release only data which comports with its a priori publicly announced policy claim that these products are "safe." Dkt. 1 ¶52.

VII. Location of the Requested V-Safe Data

The V-Safe Protocol indicates that "V-safe data will be collected, managed, and housed on a secure server by Oracle."[33] The V-Safe Protocol further provides:

> Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the secure server.[34]

Dkt. 1 ¶53.

In addition, the V-Safe Protocol states, "No PII [personally identifiable information] will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests,"[35] and that it "is anticipated that v-safe data will be shared with the scientific community."[36] Dkt. 1 ¶54.

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[33] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V6-508.pdf at 11.

[34] *Id.*

[35] *Id.*

[36] *Id.* at 15.

Once the data started being gathered, it became apparent that what was "shared with the scientific community" was CDC's cherry-picked health impact data limited to one-week post-vaccination. After public demands for release of the full dataset grew, CDC in 2022 updated the V-Safe Protocol concerning data management. Up until version 5, it provides that "A final data set at the end of the v-safe program with deidentified aggregate data will be made available for external data requests or through Freedom of Information Act (FOIA) requests."[37] The current version, version 6, now states:

> A data set with deidentified individual-level data will be created and posted twice a year to data.cdc.gov or through Freedom of Information Act (FOIA) requests. Data shared externally will go through a systematic process to remove PII and be cleared through the relevant clearance processes.[38]

Dkt. 1 ¶55.

Recently, CDC announced that it closed enrollment in v-safe for Covid-19 vaccines and that "v-safe participants will continue to have access to their account … until June 30."[39] This likely would reflect the "end of the program" as referenced in earlier protocols. And more than six months have elapsed since CDC "created and posted … [v-safe data] to data.cdc.gov."[40] Nonetheless, to date, data released to the public has been limited to the check-the-box data despite v-safe's own protocols calling for the release of all the data. Dkt. 1 ¶56.

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[37] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V5-508.pdf at 12.

[38] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-V6-508.pdf at 12.

[39] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/v-safe/index.html. (Plaintiff notes that Defendant is hereby notified to preserve all records related to the allegations in this complaint, including but not limited to the free-text fields within the COVID-19 v-safe data. Plaintiff will also send a preservation demand under separate cover.).

[40] https://data.cdc.gov/Public-Health-Surveillance/v-safe/dqgu-gg5d.

In sum, despite the foregoing claims of transparency and the purported plan to make the data public, CDC only published highly unethical and misleading studies for two years, only released the check-the-box data after being sued for same, and has now refused to release any of the critical free-text data to the public. Dkt. 1 ¶57.

The v-safe data does exist elsewhere. CDC contracted with a third party, General Dynamics Information Technology, Inc. ("**GDIT**")—for an initial amount of $6,491,148.18—to "convert[] the free text responses in v-safe to standardized MedDRA [The Medical Dictionary for Regulatory Activities] terms." Dkt. 1 at Exhibit A. This contract between CDC and GDIT reveals that all the responsive records at issue in this matter already exist in CSV (comma-separate values) format; this is how the records are sent to GDIT from CDC. What this means is that although there is a large volume of responsive records (each capped at 250 characters in length), these records are in a CSV file that already exists and that is easily searchable. Further, CDC has already agreed to pay to have individuals manually review each and every free-text field for the purpose of converting them into standardized codes. Certainly, a review for redacting any potential personally identifiable information ("**PII**") is less labor intensive than this. Query the minimal additional work that would be needed to screen for PII while every single entry is already being carefully reviewed by individuals to convert them consistently and accurately into codes. *Id;* Dkt. 1 ¶58.

To ensure that CDC expeditiously acts in furtherance of its commitment to "openness and accountability" regarding the safety of COVID-19 vaccines, and the urgency with which the scientific and medical community needs this specific data, Plaintiff made an expedited FOIA request for the critical free-text response data submitted to v-safe. Dkt. 1 ¶59.

VIII. The FOIA Request and Administrative History

On January 3, 2023, Plaintiff, through Counsel, submitted a FOIA request to CDC seeking:

> **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).** Dkt. 1 at Exhibit B.

Pursuant to 5 U.S.C. § 552(a)(6)I(i)(I), the request also sought expedited processing based on a demonstrated "compelling need." *Id*. Plaintiff also sought a waiver of fees pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" And it explained why the disclosure of the requested information would contribute to the public's understanding. *Id.*

On January 4, 2023, CDC acknowledged the request, assigned it request number 23-00462-FOIA, and denied Plaintiff's request for expedited processing, as well as Plaintiff's request for a fee waiver. *See* Dkt. 1 at Exhibit C.

On January 12, 2023, CDC issued its final determination regarding the request which stated in relevant part:

> **Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:**
>
> - **There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).**
> - **The agency lacks the resources to manually review the data collected from these registrants.**

Dkt. 1 at Exhibit D.

Notably, the agency claimed no statutory exemptions for the complete withholding.

On January 13, 2023, Plaintiff submitted an appeal challenging CDC's improper withholding of the responsive records to HHS. *See* Dkt. 1 at Exhibit E.

On January 17, 2023, CDC and HHS acknowledged the January 13, 2023 appeal and stated, in relevant part:

> Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, **your appeal falls under "unusual circumstances"** in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved. Dkt. 1 at Exhibit F (emphasis added).

On March 31, 2023, Plaintiff submitted an appeal challenging CDC's improper denial of the fee waiver, Dkt. 1 at Exhibit G, which HHS acknowledged receipt of on April 3, 2023, Dkt. 1 at Exhibit H.

CDC and HHS subsequently failed to make a final determination on these appeals within twenty business days as required by FOIA, making this matter immediately justiciable. 5 U.S.C. § 552 ("Each agency, upon any request for records … shall … make a determination with respect to any appeal within twenty [business] days … after the receipt of such appeal" and a "person making a request to any agency for records … shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph."). Dkt. 1 ¶66.

CDC and HHS also failed to make a final determination on these appeals within the ten additional business days permitted by FOIA. 5 U.S.C. § 552 (a)(6)(B)(i) ("**In unusual circumstances** as specified in this subparagraph, **the time limits prescribed** in either clause (i) or clause (ii) of subparagraph (A) **may be extended** by written notice to the person making such request setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched. **No such notice shall specify a date that would result**

in an extension for more than ten working days, except as provided in clause (ii) of this subparagraph."). Dkt. 1 ¶67.

Nor has CDC discussed with Plaintiff how it could effectively limit the scope of the request. Dkt. 1 ¶68.

Therefore, CDC has violated the time limits prescribed by FOIA and has failed to justify its complete withholding of documents responsive to Plaintiff's request. Dkt. 1 ¶69.

LEGAL STANDARD

IX. Summary Judgment

Plaintiff submits that there are no genuine issues of fact in this matter, and that it is entitled to judgment as a matter of law. Summary judgment is appropriate if no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The Court views the evidence in a light most favorable to the nonmovant. *Coleman v. Houston Indep. Sch. Dist.*, 113 F.3d 528, 533 (5th Cir. 1997). The nonmovant must go beyond the pleadings and come forward with specific facts indicating a genuine issue for trial to avoid summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986).

"FOIA cases typically and appropriately are decided on motions for summary judgment." *Defenders of Wildlife v. U.S. Border Patrol,* 623 F. Supp. 2d 83, 87 (D.D.C. 2009). "The FOIA expressly places the burden on the defending agency to sustain its action and show that it acted in accordance with the statute." *Driggers v. United States,* No. 3:11-CV-0229-N, 2011 U.S. Dist. LEXIS 152931, 2011 WL 5525337, at *3 (N.D. Tex. Oct. 26, 2011) (Ramirez, M.J.) (citing Batton, 598 F.3d at 175; Cooper Cameron, 280 F.3d at 543); see also 5 U.S.C. § 552(a)(4)(B) (". . . and the burden is on the agency to sustain its action.").

X. Freedom of Information Act, 5 U.S.C. § 552

The Freedom of Information Act, codified at 5 U.S.C. § 552, was signed into law in 1966 and gives the public right to access records from any federal agency. FOIA is intended to increase transparency and plays a critical role in keeping government transparent and accountable.

5 U.S.C. § 552(a)(3)(A) states in relevant part: "Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person." (Emphasis added.)

5 U.S.C. § 552(a)(8)(A)(i) and (ii) state: "An agency shall -- (i) withhold information under this section only if -- (I) the agency reasonably foresees that disclosure would harm an interest protected by an exemption described in subsection (b); or (II) disclosure is prohibited by law; and (ii) (I) consider whether partial disclosure of information is possible whenever the agency determines that a full disclosure of a requested record is not possible; and (II) take reasonable steps necessary to segregate and release nonexempt information." (Emphasis added.)

5 U.S.C. § 552(a)(6)(A)(ii) states in relevant part: "Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall— make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection." (Emphasis added.)

5 U.S.C. § 552(a)(6)(B)(i) states: "In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may

be extended by written notice to the person making such request setting forth the unusual circumstances for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days, except as provided in clause (ii) of this subparagraph." (Emphasis added.)

5 U.S.C. § 552(a)(6)(C)(i) states: "Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request." (Emphasis added.)

5 U.S.C. § 552(a)(4)(A)(viii) states: "Except as provided in subclause (II), an agency shall not assess any search fees (or in the case of a requester described under clause (ii)(II) of this subparagraph, duplication fees) under this subparagraph if the agency has failed to comply with any time limit under paragraph (6) … If an agency has determined that unusual circumstances apply (as the term is defined in paragraph (6)(B)) and the agency provided a timely written notice to the requester in accordance with paragraph (6)(B), a failure described in subclause (I) is excused for an additional 10 days. If the agency fails to comply with the extended time limit, the agency may not assess any search fees (or in the case of a requester described under clause (ii)(II) of this subparagraph, duplication fees) … If an agency has determined that unusual

circumstances apply and more than 5,000 pages are necessary to respond to the request, an agency may charge search fees (or in the case of a requester described under clause (ii)(II) of this subparagraph, duplication fees) if the agency has provided a timely written notice to the requester in accordance with paragraph (6)(B) and the agency has discussed with the requester via written mail, electronic mail, or telephone (or made not less than 3 good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with paragraph (6)(B)(ii)." (Emphasis added.)

ARGUMENT

I. CDC and HHS Did Not Timely Respond to Plaintiff's Appeal

As described in section VIII, *supra*, Plaintiff made a FOIA request to CDC and requested expedited processing due to the urgency of the request and compelling need for the responsive documents. CDC denied expedited processing and, soon thereafter, issued a final determination. That final determination stated that the agency was withholding the responsive documents in full. The agency did not make an attempt to discuss with Plaintiff how it could effectively limit the scope of the request. Dkt. 1 ¶70.

Plaintiff submitted an appeal on January 13, 2023 of the records denial and CDC and HHS acknowledged the appeal on January 17, 2023, stating that due to "unusual circumstances," the agency would need additional time to respond to the appeal. Pursuant to FOIA—specifically 5 U.S.C. § 552(a)(6)(A)(ii) and 5 U.S.C. § 552(a)(6)(B)(i)—the agency had 30 business days to respond. That date has come and gone and still the agency has not responded to Plaintiff's appeal. Therefore, CDC and HHS have violated FOIA and Plaintiff has exhausted its administrative remedies which led to the instant action. Dkt. 1 ¶71.

Plaintiff submitted an appeal on the fee waiver denial on March 31, 2023 and CDC and HHS acknowledged the appeal on April 1, 2023, stating that due to "unusual circumstances," the agency would need additional time to respond to the appeal. Pursuant to FOIA—specifically 5 U.S.C. § 552(a)(6)(A)(ii) and 5 U.S.C. § 552(a)(6)(B)(i)—the agency had 30 business days to respond. That date has come and gone and still the agency has not responded to Plaintiff's appeal. Therefore, CDC has violated FOIA and Plaintiff has exhausted its administrative remedies which led to the instant action. Dkt. 1 ¶72.

II. CDC is Improperly Withholding Responsive Records

CDC is improperly withholding the v-safe free-text data and has not identified a statutory exemption to justify its doing so. Recognizing that "FOIA embodies a philosophy of full disclosure by government agencies and requires them to make their records available to the public" and that "[m]oreover, [t]he FOIA was enacted to pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny," the Northern District of Texas has held that, "the exemptions an agency may claim to disclosure are explicitly limited by statute and should be construed narrowly." *Highland Capital Mgmt., LP v. IRS*, No. 3:17-cv-2906G, 2019 U.S. Dist. LEXIS 42366, at *14 (N.D.Tex. Mar. 15, 2019) (internal quotations and citations omitted). Here, the agency has failed to even identify any claimed statutory exemption to justify its complete withholding.

The need to produce this data is urgent and, as explained below, it is reasonable for CDC to timely complete production of this data. CDC has rejected this proposal. Dkt. 1 ¶73.

Plaintiff understands that the free-text data consists of responses to the following questions:

- "Enter your/their highest temperature reading from today"
- "Any other symptoms or health conditions you want to report:"

- "What type of healthcare visit did you/they have? Other - please describe:"
- "Please describe the symptoms or health conditions" or "Since your/their last check-in, have you/they experienced any new or worsening symptoms or health conditions? If yes, please describe:"

Dkt. 1 ¶74.

As is plain from these questions, they each request information regarding symptoms, not PII such as name, social security number, birth date, address, etc.[41] A user would have no plain reason to include PII in these fields since v-safe already asked for that information in separate fields (not part of the instant request). It is therefore unlikely that there would be much PII in any of the free-text fields and, in the event there is occasional PII entered by a user, there are automated programs that can search for such PII.[42] Dkt. 1 ¶75.

That said, Plaintiff certainly understands that the free-text fields will need to be reviewed for PII, likely using a mix of automated and manual review, before being produced, however CDC's defense that the "agency lacks the resources to manually review the data collected from these registrants" is without merit. Dkt. 1 ¶76. In a separate and recent FOIA matter where the plaintiffs sought close to 5 million pages of records, the district court recognized "the limited resources" that a federal agency dedicated to FOIA requests yet held that, "the number of resources

[41] For the avoidance of doubt, Plaintiff is not seeking data from any fields wherein v-safe users were prompted to enter their name, phone number, email address, or any other PII, in order to register for v-safe.

[42] *E.g.*, Microsoft has PII detection services which can be used to flag and redact, *inter alia*, names, phone numbers, addresses, email, URLs, IP addresses, age, routing numbers, credit card numbers, bank account numbers, etc. https://learn.microsoft.com/en-us/azure/cognitive-services/language-service/personally-identifiable-information/concepts/entity-categories *see also, e.g.*, https://pii-tools.com/; https://www.manageengine.com/data-security/?utm_source=comparitech&utm_medium=cpc&utm_campaign=DSP-ADTools_best-pii-scanning-tools; https://www.endpointprotector.com/; https://www.digitalguardian.com/products/data-discovery; https://www.teramind.co/product/teramind-dlp.

an agency dedicates to [FOIA] requests does not dictate the bounds of an individual's FOIA rights." *PHMPT et al. v. Food and Drug Administration*, No. 4:22-cv-00915-P, at 4 (NDTX May 9, 2023).

CDC had a discretionary budget of $8.7 billion in 2022 and a proposed discretionary budget of $10.675 billion in 2023 and there are likely few tasks, if any, it must fulfill that are more important than being transparent about the single biggest initiative over the last two years—maybe its history—of seeking to get every single American injected with a COVID-19 vaccine product, justified by the claim that they are safe and effective. Dkt. 1 ¶77.

CDC has also received special allocations from Congress regarding COVID-19, including:

- Coronavirus Response and Relief Supplemental Appropriations Act which provided **$8.75 billion** to CDC to plan, prepare for, promote, distribute, administer, monitor, and track COVID vaccines to ensure broad-based distribution, access, and vaccine coverage;
- American Rescue Plan Act which provided **$11.52 billion** to CDC to plan, prepare for, promote, distribute, administer, monitor, and track vaccines; strengthen vaccine confidence in the U.S., provide information, and improve rates of vaccination;
- Coronavirus Preparedness and Response Supplemental Appropriations Act which provided **$2.2 billion** to CDC to prevent, prepare for and respond to COVID-19; and
- CARES Act which provided **$4.3 billion** to CDC to prevent, prepare for and respond to COVID-19.[43]

Dkt. 1 ¶78.

[43] *See* https://www.cdc.gov/budget/fact-sheets/covid-19/index.html.

CDC's claim that it lacks resources to review the data, therefore, is truly incredible. The resources needed to review the v-safe free-text fields is likely a rounding error with regard to the amount CDC pays for janitorial services for its buildings. Dkt. 1 ¶79.

In the universe of the 14,703 v-safe free-text entries CDC *has* produced (from its v-safe motivation survey data, not health data), the average entry was 35 characters in length. Assuming that average per-entry character amount is the same for the free-text fields being requested here, then the 7.8 million free-text entries CDC claims it needs to review for PII[44] equates to 83,333 pages to review.[45] Dkt. 1 ¶80.

With the resources available to CDC, and the ease of reviewing for only PII in these documents, CDC should easily accomplish this task within weeks. For example, the FDA has produced over 90,000 pages a month in response to a FOIA request for the Pfizer documents provided to the FDA to license its COVID-19 vaccine, and that review required reviewing for PII and trade secrets. *See PHMPT v. FDA*, Case. No. 4:21-cv-01508-P, ECF Nos. 62 and 64. If the FDA can review 90,000 pages in a month, CDC, with triple FDA's discretionary budget, should be able to do at least that much, too. Dkt. 1 ¶81.

CDC is also well equipped and accustomed to conducting such reviews because it conducts this same type of review every day for VAERS reports. Every month since 2021 it has reviewed an average of 38,580 reports submitted to VAERS to publish the symptoms reported therein on its

[44] And it is unclear whether this 7.8 million includes "entries" of users' names, emails, and phone numbers submitted upon registration. If the 7.8 million includes those fields, those are easily segregable and do not need to be reviewed or produced which would greatly reduce the number of entries at issue.

[45] 7.8 million multiplied by 35 equals a total of 273 million characters, and dividing this number by the 3,276 average characters per page (12 font, Times New Roman, single spaced and 1 inch margins) results in 83,333 pages of text for CDC to review.

public facing VAERS system. Similarly, it can easily process the v-safe data here for PII if is so desired. Dkt. 1 ¶82.

Even if the review of the responsive documents is a heavy lift for the agency and demands resources that outweigh other FOIA requests, the agency should be made to produce the records. *See Keeping Gov't Beholden, Inc. v. DOJ*, No. 17-1569 (FYP), 2021 WL 5918627 (D.D.C. Dec. 31, 2021) ("This Court is skeptical that a FOIA request may be denied based on sheer volume of records requested alone. In fact, 'the dominant objective of FOIA is disclosure, and exemptions are to be narrowly construed.' FOIA puts no restrictions on the quantity of records that may be sought, but rather anticipates requests for voluminous records.") (internal citations omitted). Dkt. 1 ¶83.

Plaintiff is not demanding a fishing expedition to locate responsive documents; it has made a specific request for an identifiable and easily located universe of documents that are directly related to Plaintiff and the public's interests. Taxpayers paid for v-safe to track the safety of products. Taxpayers also funded development and manufacturing of many of these vaccines. They paid to purchase them, and had these products mandated on them under threat of losing their jobs, going to school, being discharged from the miliary, and being excluded from parts of civil society, often as a direct result of federal government mandates. As a result, they are entitled to the data that is requested by Plaintiff even if it comes at an additional cost. This data cannot be obtained through any other sources, it cannot be replicated, and is therefore priceless. Dkt. 1 ¶84.

The reality, however, is that CDC can easily process the current request. Indeed, it requires suspending reality to believe that CDC lacks the resources to review the v-safe data for PII. **The real reason CDC is objecting to producing this data is it does not want to make it public.** CDC does *not* want the public to scrutinize its claims. It wants to do precisely what FOIA finds

abhorrent: kill transparency and prevent the public from have visibility into its claim that COVID-19 vaccines are "safe and effective," a claim used to crush the civil and individual rights of millions of Americans over the last two years, often at CDC's recommendation or encouragement. Dkt. 1 ¶85.

CDC plainly believes that its decisions should face no public scrutiny. That what it recommends should be treated as gospel. That everyone needs to do what it says without question. CDC has plainly forgotten it still works for the American people and not the other way around. Dkt. 1 ¶86.

III. CDC improperly denied the fee waiver

Pursuant to 5 U.S.C. § 552(a)(4)(A)(iii), fees must be waived where "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" The disclosure of the requested information will and would contribute to the public's understanding in at least three ways: (1) the disclosure of the requested information will provide the public with primary source documentation of the reactions v-safe participants experienced during regularly set intervals after receiving various doses of the COVID-19 vaccines originally approved under the government issued Emergency Use Authorization; (2) this data will shed light on the overall safety and efficacy of the COVID-19 vaccines for the over 10 million v-safe participants, a substantial sample size to synthesize important information regarding the vaccines' safety and efficacy; and (3) the disclosure of the information described above will shed light on whether CDC and other health agencies appropriately monitored and acted upon the information provided by v-safe participants. The information the organization requests will not contribute to any commercial activities. Dkt. 1 ¶87. CDC therefore erred in its denial of the fee waiver. Dkt. 1 ¶88.

CONCLUSION

CDC has clear obligations pursuant to FOIA, an act implemented for situations precisely like this one. CDC used taxpayer dollars to collect information from Americans about a product that American taxpayers funded and were, in many situations, mandated to take. CDC has violated FOIA in its denial of Plaintiff's initial request, in its refusal to respond to Plaintiff's appeal, in wrongly denying Plaintiff's fee waiver, and in its representation that, absent a court order, it will not produce the data. Plaintiff implores this Court for that Order. Accordingly, Plaintiff respectfully requests this Court to grant its motion for summary judgment.

Dated: July 11, 2023

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CERTIFICATE OF SERVICE

I certify that I have served a copy of the foregoing upon the Defendants, through CM/ECF, and by ordinary U.S. mail to the parties and their Counsel, this 11 day of July, 2023.

/s/Christopher Wiest